DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

George Houser, Owner
Brotherhood Farms
1415 State Route 40
Greenwich, NY 12834

July 22, 2004

Ref: NYK-2004-23

Dear Mr. Houser:

An investigation at your dairy farm located in Greenwich, New York, conducted by a Food and Drug Administration investigator on March 30, 31, and April 6, 2004, confirmed that you offered animals for slaughter as food that were adulterated within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ("the Act"). The inspection also revealed that you also caused medicated animal feed to become adulterated within the meaning of Section 501(a)(6) of the Act.

On or about November 3, 2003, you consigned a bob veal calf (identified by U.S. Department of Agriculture ("USDA") Sample No. 425445, tag no. "G266", and retain tag no. "MPD-45568588") for slaughter for human food through [redacted] located in [redacted] USDA's Food Safety and Inspection Service ("FSIS") analysis of tissue samples collected from that animal found 1.82 ppm of the drug neomycin in kidney tissue. There is no established tolerance for residues of neomycin in the edible tissues of calves (21 CFR 556.430). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about November 17, 2003, you consigned a bob veal calf (identified by USDA Sample No. 939631, tag no. "G441", and retain tag no. "MPD-46344339") for slaughter for human food through [redacted] located in [redacted] USDA's FSIS analysis of tissue samples collected from that animal found 0.80 ppm of the drug neomycin in kidney tissue. There is no established tolerance for residues of neomycin in the edible tissues of calves (21 CFR 556.430). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions, which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that medicated animal feed is used in a manner not contrary to labeling instructions and for assuring that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you failed to record the treatment records of calves #G266 and #G442. Treatment records should, at a minimum, identify the animals treated, the dates of treatment, the drugs/medicated animal feeds administered, who administered the drugs/medicated animal feeds, the amounts administered, and the withdrawal times prior to slaughter and/or when milk can be used. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Moreover, your actions caused the medicated feed [redacted] which contains the drug neomycin, to become adulterated within the meaning of Section 501(a)(6) of the Act when you used it in calves to be processed for veal contrary to the warning on the feed's label. Because the Act does not permit the extralabel use of medicated feeds, your actions caused the medicated feed to be unsafe to use under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.

The above is not an all-inclusive list of violations existing at your farm. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

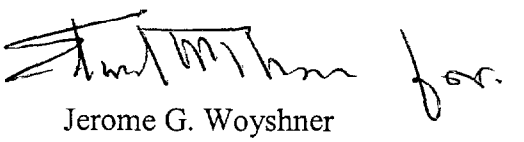
You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, such as seizure and/or injunction, without further notice.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions regarding this letter, you can contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,



Jerome G. Woyshner
District Director